

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER U.S. Food and Drug Administration 555 Winderley Place Suite 200 Maitland, FL 32751 Phone: 407-475-4700 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 6/5-8/2017
	FEI NUMBER 3003785869

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Samuel D Pratt, President

FIRM NAME Pharmacy Specialists of Central FL Inc dba Pharmacy Specialists	STREET ADDRESS 393 Maitland Ave.
CITY, STATE AND ZIP CODE Altamonte Springs, FL 37201	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1:

Hazardous and highly potent drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination:

Specifically, these drug products are prepared and handled without providing adequate cleaning and sanitization of work surfaces and reusable equipment such as spatulas, stainless steel spoons, unguator jars, mixing mill equipment, and the unguator (b) (4) to prevent cross-contamination. Your operations include the preparation of non-sterile drug products that contain anti-neoplastic agents such as fluorouracil and hormones such as testosterone using reusable equipment that is (b) (4) cleaned using either municipal water, dish detergent, reverse osmosis water rinse, and (b) (4) or a (b) (4) (b) (4) of the mixing mill equipment used to prepare topical drug products. You do not show that these methods are effective in removing these drug residues. Examples of these preparations are as follows:

- A. Fluorouracil 5 % cream lot (b) (4) used to prepare 5-fluorouracil 2.5% /calcipotriene 0.0025% cream lot (b) (4)
- B. Testosterone USP lot (b) (4) used to prepare testosterone 50 mg/chrysin 25 mg/progesterone 10 mg KE cream lot (b) (4)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joanne E. King -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Joanne E. King, Investigator	DATE ISSUED 06/08/2017
	<small>Digital signed by Joanne E King S DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People cn=Joanne E King, s=9 2342 10200300 100 11-1300174867 Date: 2017.06.08 11:01:05 -0400</small>		